REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 12, 27, 37 and 40-47 are pending in the application and have been rejected.

Claim 37 has been amended in this submission. Applicants respectfully assert that the amendments to the claims add no new matter.

CLAIM REJECTIONS

35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 12, 37 and 40-47 under 35 U.S.C. § 103(a), as being unpatentable over Iddan et al. (U.S. Patent No. 5,604,531) in view of Kaye et al. (U.S. Patent No. 3,939,823) and Yoon (U.S. Patent No. 6,419,626). According to the Examiner, Iddan et al. disclose a pressure sensor but fail to disclose the sensor including a pliant sleeve surrounding the shell and defining a space between the shell and the sleeve that is filled with a dielectric liquid in which a pressure gauge is immersed. The Examiner alleges that Kaye, which teaches an esophageal transducer, discloses these elements, referring to column 2, lines 47-65 thereof. The Examiner states that the claims would have been obvious because both Iddan and Kaye teach in vivo measuring devices, and it would have been obvious at the time to substitute one pressure measuring sensor for another to achieve the predictable results of obtaining better reassure measurements within internal body cavities. Applicants respectfully traverse this rejection.

Applicants first contend that the Kaye reference is not combinable with the Iddan reference so as to render the pending claims obvious. Kaye teaches an esophageal transducer, which is inserted into the esophagus at the end of a catheter that maintains its physical connection to outside of said patient's body at all times, and measures pressure on the

catheter due to esophageal contractions. The transducer has a gap between front and back body portions thereof that contains pins to hold together the front and back portions and that is surrounded by a pliant sleeve that defines a space whose entire remaining volume is filled with a liquid in which a pressure gauge is immersed. The catheter has an elongated shape and, when fitted with the transducer as described in Kaye is able to sense pressure applied by the body lumen along a large length of the catheter.

However, by contrast, Iddan discloses (and the present claims require) a swallowable in vivo imaging device that, because it has no physical connection to outside of said patient's body when swallowed within a patient's lumen, has certain practical size limitations that render the Kaye pressure sensor irrelevant to Iddan and to the present invention. Because such an autonomous in vivo device must be swallowable, it must be small, typically about 1 inch in total length. The dome shaped optical window of the capsule occupies a portion of the length and volume, leaving a capsule shell that is shorter than 1 inch. In addition, because the autonomous in vivo device must also house batteries that have sufficient power capacity to last during the entire time of passage through the body lumen as well as other electrical components, such as an imager, a transmitter and an antenna, there is precious little space along the length of the device to spare for a gap such as disclosed in Kaye.

As a result, even if Kaye is combined with Iddan, the gap in the catheter as disclosed in Kaye would be very difficult to accomplish in the swallowable in vivo device of Iddan while still maintaining the specific practical size limitations, as such a gap would have to be very small so as not to add much to the overall length of the in vivo device to be swallowed. Moreover, if implemented, such a small gap would most likely not be large enough to continuously identify pressure from the walls of the body lumen, e.g., the small intestine, since such pressure comes in intervals, is not necessarily spread equally on the entire body of the capsule, and may not necessarily be incident on the small length of the gap. Specifically, if the gap of Kaye would be incorporated into the in vivo device of Iddan, pressure from the walls of the body lumen would have to be applied to the swallowable in vivo device with almost a pin prick's accuracy specifically at the exact location of the gap in order to be sensed. This is, of course, highly unlikely

However, the considerations that dictate significant size restrictions on an autonomous in vivo device do not exist in an elongated catheter, as in Kaye, that maintains its physical connection to outside of said patient's body at all times. Therefore, the pressure gauge gap as described in Kaye would likely not be operable in a swallowable in vivo device. As such, one with skill in the art of swallowable in vivo devices would not look to Kaye as providing a solution or a way to use the swallowable in vivo device to sense pressure in the body lumen, since such a skilled person would understand that the pressure sensing catheter device disclosed in Kaye is not combinable with the swallowable device disclosed in Iddan.

Instead, as the inventors hereof have discovered that, for a swallowable in vivo device, it is beneficial to use the surface of the entire capsule body as a pressure gauge. Namely, the pliant sleeve surrounds the outside shell of the device and incorporates a fluid between the sleeve and the shell.

Accordingly, Applicants have amended independent claim 37 to clarify the manner in which the present invention accomplishes its pressure sensing, which is different from how it is accomplished in Kaye. Amended independent claim 37 now recites a swallowable in vivo imaging device that, "when swallowed within a patient's lumen, has no physical connection to outside of said patient's body" and comprises "a housing including an optical dome, a shell enclosing components of said device, and a pliant sleeve surrounding said shell, said pliant sleeve defining a space outside the shell and inside the pliant sleeve, said space being filled with a fluid" and "an imaging system enclosed in said shell behind said optical dome". The device required in amended independent claim 37, as shown in Figure 8, has a device with a shell that surrounds and contains the elements of the device, and the fluid is contained within a pliant sleeve but outside the shell. That is to say, the fluid is contained between the pliant sleeve and the shell and is not within the volume of the device shell.

By contrast, Kaye does not show fluid surrounding the shell in the same way as required in amended independent claim 37. In Kaye, by contrast, the fluid is within a cavity 15 encompassed by the flexible sleeve 38 within which are pins 20 that hold the front and back end portions 14,16 of the device together, such that the fluid is within the entire cross-sectional volume of the catheter between the front and back portions. Thus, Kaye does not disclose or suggest an in vivo device comprising "a housing including an optical dome, a

shell enclosing components of said device, and a pliant sleeve surrounding said shell, said pliant sleeve defining a space outside the shell and inside the pliant sleeve, said space being filled with a fluid" and "an imaging system enclosed in said shell behind said optical dome".

Accordingly, Applicants respectfully assert that amended independent claim 37 is allowable. Claims 12 and 40-47 depend from independent claim 37, directly or indirectly, and therefore include all the limitations of that claim. Therefore, Applicants respectfully assert that dependent claims 12 and 40-47 are likewise allowable. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections to amended independent claim 37 and to claims 12 and 40-47 dependent thereon.

In the Office Action, the Examiner rejected claim 27 under 35 U.S.C. § 103(a), as being unpatentable over Iddan et al. in view of Kaye et al. and Yoon as applied to claim 37, in further view of D'Andrea et al. (U.S. Patent Application Publication No. 2003/0191430).

Claim 27 depends from independent claim 37, directly or indirectly, and therefore includes all the limitations of that claim. Because amended independent claim 37 is allowable over the combination of Iddan et al. in view of Kaye et al. and Yoon as discussed above, and D'Andrea et al. do not solve the deficiencies of Iddan et al., Kaye et al. and Yoon, amended independent claim 37 is allowable over the combination of Iddan et al. in view of Kaye et al. and Yoon as applied to claim 37, in further view of D'Andrea et al. Therefore, Applicants respectfully assert that dependent claim 27 is likewise allowable, and Applicants respectfully request that the Examiner withdraw the rejection to dependent claim 27.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

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